



JUN 18 2003

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Teri Juckett  
Regulatory Affairs Manager  
AngioDynamics, Inc.  
603 Queensbury Avenue  
Queensbury, New York 12804

Re: K031233  
Trade/Device Name: AngioDynamics, Inc. ELVS Procedure Kit  
Regulation Number: 21 CFR 878.4810  
Regulation Name: Laser surgical instrument for use in general  
and plastic surgery and in dermatology  
Regulatory Class: II  
Product Code: GEX  
Dated: April 16, 2003  
Received: May 6, 2003

Dear Ms. Juckett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

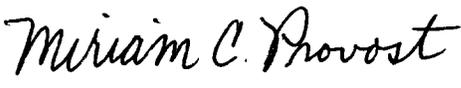
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Ms. Teri Juckett

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

*for* 

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

### INDICATIONS FOR USE

**510(k) Application:** Traditional 510(k)

**Device Name:** AngioDynamics, Inc. ELVS Procedure Kit

**Indications for Use:**

The AngioDynamics, Inc. ELVS Procedure Kit is indicated for endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux and is also indicated for the treatment of varicose veins and varicosities associated with superficial reflux of the greater saphenous vein.

The AngioDynamics, Inc. ELVS Procedure Kit is indicated for use with 810 nm and 980 nm Diode Lasers with SMA 905 connectors.

Miriam C. Provost  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K63/233

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use X

OR Over-the-Counter Use

(Per 21 CFR 801.109)